Complete Summary

GUIDELINE TITLE

Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot.

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 25. 9 p. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diastolic dysfunction after tetralogy of Fallot repair

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Pediatrics

Pharmacology
Surgery
Thoracic Surgery

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide a clinical guideline for the use of inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot (TOF)

TARGET POPULATION

These guidelines are intended for use in infants and children who have undergone complete repair of tetralogy of Fallot (TOF).

Note: The guidelines do not address all considerations needed to manage those with significant hypotension.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Physical exam
2. Monitoring of urine output
3. Blood work for metabolic acidosis or lactic acidemia
4. Continuous monitoring of arterial blood pressure via an arterial line
5. Continuous monitoring of right and left atrial pressure with a transthoracic or internal jugular/subclavian vein catheters

Treatment with Phosphodiesterase Inhibitors

1. Inamrinone
2. Milrinone

MAJOR OUTCOMES CONSIDERED

- Cardiac output
- Oxygen levels

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Based Grading Scale:

A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis
E: Expert opinion or consensus
F: Basic laboratory research
S: Review article
M: Meta-analysis
Q: Decision analysis
L: Legal requirement
O: Other evidence
X: No evidence

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this document were formulated by a working group that included community and hospital based physicians, nurses, and pharmacists, who examined current local clinical practices and performed extensive and critical literature reviews.

During formulation of these guidelines, the committee members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by senior management, Legal Services, the Institutional Review Board, the hospital's Pharmacy and Therapeutics, Clinical Practices, Executive, and other committees and other individuals as appropriate to their intended purposes.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades (A-X) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Clinical Assessments

1. It is recommended that cardiac index be supported to maintain normal to minimally elevated right atrial pressure or central venous pressure (CVP) (5–15 mm Hg) with evidence of adequate tissue and organ perfusion as defined by physical exam, urine output >1 cc/kg/min and in the absence of metabolic acidosis or lactic acidemia (Charpie et al., 2000 [C]; Munoz et al., 2000 [C]).

   Note 1: Ongoing metabolic acidosis caused by the continued production of lactic acid has been associated with a poor outcome following cardiac surgery in infants and children (Charpie et al., 2000 [C]; Munoz et al., 2000 [C]).

   Note 2: Continuous monitoring of arterial blood pressure via an arterial line is recommended. [E].

Note 3: Continuous monitoring of right and left atrial pressures with transthoracic or internal jugular/subclavian vein catheters is recommended [E].

Treatment Recommendations

1. It is recommended that a phosphodiesterase inhibitor (PDEI) be considered for any patient following tetralogy of Fallot (TOF) repair to prevent the occurrence of low cardiac output due to restrictive right ventricular physiology after TOF repair. (Expert consensus [E]; Saal et al., 1994 [C]).

   Note: There is no direct evidence to suggest that routine use of inamrinone/milrinone following TOF repair improves outcome, but this recommendation is based on evidence that restrictive right ventricular physiology is associated with increased morbidity after TOF repair and that phosphodiesterase inhibitors improve left ventricular diastolic function (Pagel, Hettrick, & Warltier, 1993 [F]; Werner, Herbertson, & Walley, 1995 [F]; Cullen, Shore, & Redington, 1995 [C]; Norgard et al., 1996 [C]; Berner et al., 1990 [C]; Chang et al., 1995 [C]).

2. It is recommended that inamrinone be started for any patient with a right atrial pressure greater than 15mm Hg or with signs or symptoms of low cardiac output. The standard loading dose of amrinone is 1–3 mg/kg over 30 to 60 minutes followed by an infusion at 5–10 micrograms/kg/min (Hamada et al., 1999 [B]; Kikura et al., 1998 [C]; Rathmell et al., 1998 [B]).

   Note 1: If inamrinone is loaded on cardiopulmonary bypass, a loading dose of up to 4 mg/kg may be necessary because of the high volume of distribution (Lawless et al., 1989 [C]).

   Note 2: If hypotension develops, blood pressure support with other inotropic/vasopressor agents may be necessary (Lynn et al., 1993 [C]).

3. Milrinone may serve as an effective alternative to inamrinone. The usual loading dose of milrinone is 50 micrograms/kg over 30 to 60 minutes followed by an infusion at 0.375–0.75 micrograms/kg/min (Hamada et al., 1999 [B]; Rathmell et al., 1998 [B]).

   Note: Direct comparison has failed to show any significant hemodynamic differences between inamrinone and milrinone. There are anecdotal reports of less thrombocytopenia with milrinone, so milrinone may be particularly useful for patients in whom phosphodiesterase inhibition is desired, but who are thrombocytopenic (Hamada et al., 1999 [B]; Rathmell et al., 1998 [B]).

Definitions:

Evidence Based Grading Scale:

A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series

D: Retrospective analysis
E: Expert opinion or consensus
F: Basic laboratory research
S: Review article
M: Meta-analysis
Q: Decision analysis
L: Legal requirement
O: Other evidence
X: No evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific recommendations in this guideline are drawn from directly applicable studies where possible, but are largely extrapolated from smaller studies, and from studies more indirectly related to the present issues.

The type of evidence is identified and classified for each recommendation (see "Major Recommendations") using the following scheme:

Evidence Based Grading Scale:

A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis
E: Expert opinion or consensus
F: Basic laboratory research
S: Review article
M: Meta-analysis
Q: Decision analysis
L: Legal requirement
O: Other evidence
X: No evidence

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improvement in right ventricular diastolic function

POTENTIAL HARMS

Hypotension may develop when using inamrinone, which may necessitate blood pressure support with other inotropic/vasopressor agents.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- In developing this guideline, the working group recognizes the paucity of large-scale studies with direct bearing on this particular focus population. The specific recommendations in this guideline are drawn from directly applicable studies where possible, but are largely extrapolated from smaller studies, and from studies more indirectly related to the present issues.
- These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The implementation process for each Cincinnati Children's Hospital Medical Center (CCHMC) guideline is a phase in a larger process of Guideline Development. This process is utilized for every guideline but is not addressed in the content of every guideline.

At the start of each guideline, a projected implementation date is determined. Reservations for education are then made (Grand Rounds, Patient Services Inservices). When the guideline is complete and enters into the Approval Process, Education planning begins. Changes created by the guideline are outlined as well as anticipated outcomes. The implementation date is confirmed. Education is provided. The guideline is implemented and pilot information collection started. The Guideline Coordinator makes daily rounds and eligible children are followed to document the use of the guideline. The implementation phase aids in finding areas for improvement or question. When issues identified are improved the guideline progresses to the monitoring phase.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 25. 9 p. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 25

GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

Members of the Cardiac Clinical Pathway Development Team 2000

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Cincinnati Children's Hospital Medical Center.

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at HPCEInfo@chmcc.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Home care. Heart surgery after care. Cincinnati Children's Hospital Medical Center, 2004.

Available from the Cincinnati Children's Hospital Medical Center Web site.

NGC STATUS

This NGC summary was completed by ECRI on August 24, 2004. The information was verified by the guideline developer on October 12, 2004.

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